REMARKS

Status of the Claims

Claims 1-43 are pending in this application, and subject to a Restriction Requirement. New claims 44-54 are submitted herein. No claims are cancelled. After entry of this amendment, **claims 1-54 will be pending**.

Claim 1 is amended to specify that the flavivirus antigen is from a second flavivirus or the flavivirus antigen is a chimeric antigen comprising amino acid sequence from more than one flavivirus. Support for this amendment can be found, for example, at page 13, lines 4-11; page 18, lines 1-15; page 31, line 19 to page 32, line 3; and in Example 20, beginning on page 65 of the specification. Claims 3 and 19 are amended to add St. Louis encephalitis virus to the list of recited flaviviruses, support for which can be found throughout the specification and claims as originally filed. Claim 19 is further amended for clarity and proper antecedent basis. Claims 8, 9, 20 and 21 are amended to remove "of a flavivirus" for clarity and proper antecedent basis. Claim 14 is amended for proper antecedent basis. Claims 28-37 are amended to replace "is" with "comprises." Support for new claims 44-54 can be found throughout the specification and claims as originally filed. Specifically, support for a modified Japanese encephalitis virus signal sequence can found, for example, on page 19, lines 16-21; page 30, line 24 to page 31, line 2; and page 32, lines 13-22. Support for claims 45-54 can be found, for example, at page 13, lines 4-11; page 18, lines 1-15; page 31, line 19 to page 32, line 3; and in Example 20, beginning on page 65 of the specification. No new matter has been introduced by these amendments.

Response to Restriction Requirement

Claims 1-43 are subject to a restriction requirement. In particular, the following Groups have been designated:

Group I	Claims 1-16, 28, 30, 32, 34 and 36 (and new claims 44-54) Drawn to nucleic acids encoding recombinant flavivirus antigens
Group II	Claim 17 Drawn to a composition comprising a nucleic acid and carrier
Group III	Claims 18-27, 29, 31, 33, 35 and 37 Drawn to immunization methods employing a nucleic acid flavivirus vaccine
Group IV	Claim 38 Drawn to a recombinant flavivirus antigen

Group V	Claims 39 and 42 Drawn to an antibody capture assay employing a recombinant flavivirus antigen
Group VI	Claim 40 Drawn to a flavivirus-specific antibody
Group VII	Claims 41 and 43 Drawn to an antigen capture assay employing a flavivirus-specific antibody

Applicant **traverses** the requirement for restriction. The Office alleges that each Group of claims relates to a distinct invention. This application is a National Stage application filed under 35 U.S.C. §371. As such, the application is entitled to examination according to the unity of invention standard. Applicant requests that the requirement for restriction be withdrawn in light of the arguments herein.

Standard for Analyzing Unity of Invention

37 CFR § 1.475 requires unity of invention in a national stage application such as this; unity of invention is present when a group of inventions are "so linked as to form a single general inventive concept." [*See* 37 CFR § 1.475(a).] "A group of inventions is considered linked to form a single general inventive concept where there is a technical relationship among the inventions that involves at least one common or corresponding special technical feature." [MPEP § 1893.03(d). *See also* 37 CFR § 1.475(a).]

Further, "The expression 'special technical features' shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art." [*See* 37 CFR § 1.475(a).]

This makes it clear that an analysis with regard to unity of invention occurs in two stages. First, is there a special technical feature shared among the claims/groups of inventions, such that they are linked to form a single inventive concept? If there is, then one asks does that special technical feature **define a contribution over the prior art** for each of the claimed inventions? If no relevant prior art is identified, then there can be no finding of lack of unity.

Applying the Standard in the Current Case

Groups I through VII are linked to form a single general inventive concept. The claims all relate to transcriptional units encoding immunogenic flavivirus antigens. They further relate

to use of the transcriptional units encoding flavivirus antigens as vaccines and detecting an immune response to the flavivirus antigens. This general inventive concept is clear from the title of the application (Nucleic Acid Vaccines for Prevention of Flavivirus Infection) and the Abstract, which states that the invention encompasses nucleic acids comprising "transcriptional units which encode…an immunogenic flavivirus antigen," "antigens encoded by the nucleic acids," "a nucleic acid and protein vaccine," "use of the vaccine to immunize a subject against a flavivirus infection," antibodies elicited in response to the immunogenic flavivirus antigens and use of the antigens or antibodies for detection or diagnosis.

It is further clear that a special technical feature is shared among all of the claims. The special technical feature of **a transcriptional unit encoding a signal sequence of a structural protein of a first flavivirus and an immunogenic flavivirus antigen, wherein the antigen is of a second flavivirus or is a chimeric antigen comprising amino acid sequence from more than one flavivirus** is *explicitly* recited in all claims (all claims depend directly or indirectly from claim 1 which recites this special technical feature). All dependent claims directed to immunization methods, antigens, antibodies and capture assays depend from claim 1 and thus necessarily incorporate all features of claim 1.

Moreover, Applicant submits this special technical feature defines a contribution over the prior art for each of the Groups of claims. No reference has been cited in the current Restriction Requirement, which would appear to be a clear admission that there is no relevant prior art.

Since the Office has provided neither allegation nor evidence that the claimed transcriptional units are disclosed or rendered obvious by the prior art, this feature clearly constitutes an appropriate "corresponding special technical feature" sufficient for the fulfillment of the unity of invention requirement. [*See* 37 CFR § 1.475(a); MPEP § 1893.03(d).]

Applicant further notes that "Unity of invention has to be considered in the first place only in relation to the independent claims . . . and not the dependent claims." (See "Unity of Invention", Section (c), Annex B to the Administrative Instructions under the PCT, at page AI-55, MPEP (Rev. 4, October 2005). Further, in section (c)(i) it is clearly stated that:

> If the **independent claims avoid the prior art** and satisfy the requirement of unity of invention, **no problem of lack of unity arises in respect of any claims that depend on the independent claims**. In particular, it does not matter if a dependent claim itself contains a further invention. Equally, no problem arises in the case of a genus/species situation where the genus claim avoids the prior art. Moreover, no problem arises in the case of a combination/subcombination

situation where the subcombination claim avoids the prior art and the combination claim includes all the features of the subcombination. (*emphasis added*)

In the pending claims, claim 1 is the only independent claim. Claims 2-43 (and new claims 44-54) depend directly or indirectly from claim 1, and therefore include all the features of claim 1, including the transcriptional unit encoding a signal sequence of a structural protein of a first flavivirus and an immunogenic flavivirus antigen, wherein the antigen is of a second flavivirus or is a chimeric antigen comprising amino acid sequence from more than one flavivirus.

In summary, **as required by 37 CFR §1.475**, the claims pending in the application have unity of invention because they are directed "to a group of inventions so linked as to form a single general inventive concept" because "there is a technical relationship among [the] inventions involving one . . . corresponding technical feature" – **transcriptional unit encoding a signal sequence of a structural protein of a first flavivirus and an immunogenic flavivirus antigen, wherein the antigen is of a second flavivirus or is a chimeric antigen comprising amino acid sequence from more than one flavivirus** – and this special technical feature "define[s] a contribution . . . over the prior art."

Since unity of invention exists among all of the Groups in the present application, it is inappropriate to subject the claims to a requirement for restriction. Applicant requests that the requirement be withdrawn, that all of Groups I through VII be rejoined, and that all of the claims be examined in the current case.

However, if Applicant's arguments are not persuasive in regard to withdrawing the requirement for restriction among Groups I through VII, Applicant requests rejoining of at least Groups I and II. The claims of Group I are directed to nucleic acids encoding recombinant flavivirus antigens. Group II consists of a single claim (claim 17) directed to compositions comprising the nucleic acids (of Group I) and a pharmaceutically acceptable carrier. Contrary to the assertion made by the Office, the compositions of Group II would not require an additional search. Furthermore, the compositions of Group II and the nucleic acids of Group I do not have different modes of operation, different functions, or different effects. Therefore, Applicant submits Group I and Group II should be rejoined. In addition, since Groups II and III are related as product and process, Applicant submits Group I also is related to Group III as product and process. Accordingly, upon allowance of product claims from either Group I or Group II (as

currently designated in the Restriction Requirement), Applicant is entitled to rejoinder of the process claims (Group III).

Although Applicant traverses the requirement for restriction, in order to provide a complete reply to the Restriction Requirement, Applicant hereby elects Group I, claims 1-16, 28, 30, 32, 34, and new claims 44-54. In accord with 37 C.F.R. §1.143, Applicant specifically reserves the right to petition to have the appropriateness of the finding of lack of unity/restriction requirement reconsidered, if it is maintained in spite of this response.

CONCLUDING STATEMENT

Substantive examination of the pending claims is requested. The Examiner is encouraged to telephone the representative for Applicant listed below if the Examiner believes that a telephone interview would facilitate substantive examination of this application.

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